AMENDMENT UNDER 37 C.F.R. § 1.116
U.S. Application No. 09/125,814

Claim 24 (Amended), lines 15-18: Replace "on/in" (all occurrences) with -- on or in --.

Claim 25 (Amended), lines 15-18: Replace "on/in" (all occurrences) with -- on or in --.

REMARKS

Claims 19-32, 34 and 36-45 are all the claims pending in the application. Applicants have amended claims 19, 24 and 25 for purposes of clarity. Entry of the above amendments is respectfully requested.

I. Rejection of claims 19-32, 34 and 36-45 under 35 U.S.C. § 112

On page 2 of the Office Action, the Examiner rejects claims 19-32, 34 and 36-45 under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention.

The Examiner asserts that several words, such as hydroxyothyl cellulose and hydroxyethyl cellulose at line 7 and chisosan at line 12, are misspelled in claim 19 so that it is unclear what Applicants intend to claim. In addition, the Examiner asserts that the term "on/in" in claims 24 and 25 renders the claims indefinite because it is unclear how the drug can be dispersed on and in the bases. The Examiner asserts that the addition of a drug dissolved in water to a water-absorbing material would result in the solubilized drug being absorbed in the water-absorbing material.

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The Examiner will note that Applicants have replaced "hydroxyothyl cellulose" with --hydroxyethyl cellulose--, deleted "hydroxysthyl cellulose", and replaced "chitosan" with --chitosan-- in claim 19. In addition, Applicants have amended claims 24 and 25 by replacing "on/in" with --on or in--.

In view of the above, Applicants respectfully request that the rejection be withdrawn.

II. Rejection of claims 19-16, 28-32, 34 and 36-45 under 35 U.S.C. §102/103

On pages 3-4 of the Office Action, the Examiner maintains the rejection of claims 19-25, 28-32, 34 and 36-45 under 35 U.S.C. § 102(b) as allegedly being anticipated by or, in the alternative, under 35 U.S.C. § 103(a) as allegedly obvious over Suzuki et al. (U.S. Patent 4,613,500).

The Examiner cites Suzuki et al. as disclosing a powdery composition comprising a polypeptide that is absorbed onto or into a water-absorbing and water-insoluble base. *See* col. 2, line 57 to col. 3, line 25; col. 4, lines 21-41; and col. 5, lines 52-65. The Examiner asserts that this composition may be combined with a water-absorbing and water-soluble (gel-forming) base. *See* col. 5, lines 10-25. In addition, the Examiner asserts that a product obtained by a particular process is not considered patentable over the prior art product absent evidence of superior and unexpected results, and that none of the claims require that the product be made by the processes disclosed.

On page 4 of the Office Action, the Examiner asserts that Suzuki et al. teaches that the drug is dispersed on or in the water-absorbing and water-insoluble base at col.

5, lines 53-65. In addition, the Examiner asserts that although Suzuki et al. teaches that a water absorbing and water-soluble (gel-forming) base may be added, it is silent as to whether or not the drug is dispersed on or in this base. Therefore, it is the Examiner's position that the composition of Suzuki et al. obtains uneven dispersion of the drug as claimed.

Furthermore, the Examiner asserts that the graph does not clearly show what is being measured and graphed in order to determine unexpectedly superior results. The Examiner further asserts that Applicants have not presented any data to show that a different product is obtained by Applicants' process than by the process of Suzuki et al., and that none of the claims require any of the processes disclosed in the instant application.

In response, Applicants respectfully traverse this rejection for the following reasons.

Suzuki discloses that the drug is dispersed on the base at col. 5, lines 56-59; that the drug is dispersed in the base at col. 5, lines 59-62; and that the drug is dispersed closely to the base at col. 5, lines 62-64. Suzuki continues to disclose that in each of the compositions, a uniform dispersion is formed. Therefore Suzuki does not teach or suggest an unevenly dispersed drug on or in the base material, and hence does not anticipate the present invention.

In addition, in the graph in Attachment B, Applicants compared the present invention to Example 1(b) of Suzuki. As a result, the present invention exhibits unexpectedly higher plasma drug levels than Suzuki due to the uneven dispersion of

the art. Applicants further showed that the present invention with the unevenly distributed drug exhibits higher levels of absorption than Suzuki.

Furthermore, Applicants compared the plasma drug level of the present invention with that of the conventional art (e.g., prior to Suzuki's invention). In attachment B, "1" shows the plasma drug level of the powder manufactured by the conventional method. "2" shows the plasma drug level of the powder manufactured by Suzuki's method, specifically Example 1(b) of Suzuki, which shows sustained release of the drug. "3" shows the plasma drug level of the powder manufactured by the present invention, and shows the highest absorption level of the three. Such high absorption level of the present invention is a result of uneven dispersion of the drug.

The above results show that the distribution of the drug in the powder significantly influences the plasma drug level. The drug unevenly distributed to the water-absorbable and -insoluble base is the best absorbed. Therefore, Applicants submit that the drug absorption of the present invention is unexpectedly higher than that of the composition of Suzuki.

In view of the above, Applicants respectfully submit that Suzuki fails to teach or suggest the present invention, and hence does not render the present invention obvious. Accordingly, Applicants respectfully request that the rejection be withdrawn.

III. Rejection of claims 19-32, 34 and 36-45 under 35 U.S.C. § 103(a)

On page 5 of the Office Action, the Examiner maintains the rejection of claims 19-32, 34 and 36-45 under 35 U.S.C. § 103(a) as allegedly being unpatentable over Suzuki et al. in view of Makino et al. (U.S. Patent 5,262,871).

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The Examiner acknowledges that Suzuki et al. does not teach the use of non-peptide non-proteinaceous drug. The Examiner cites Makino et al. as disclosing non-peptide non-proteinaceous drugs for use in powdery nasal compositions. *See* col. 7, line 10 - col. 8, line 26 and col. 4, lines 11-13. According to the Examiner, it would have been obvious to one of ordinary skill in the art at the time of the invention to substitute a non-peptide/non-proteinaceous drug as taught in Makino et al. for a peptide/proteinaceous drug in the composition of Suzuki with the reasonable expectation of producing a powdery nasal composition. The Examiner asserts that the motivation to do so stems logically from the art-recognized desire for a medicament that is efficiently absorbed through the nasal mucosa.

In addition, on page 6 of the Office Action, the Examiner asserts that Makino et al. is cited to show that it is known in the art to use non-peptide/non-proteinaceous drugs in powdery nasal compositions and that it would, therefore, have been obvious to substitute a non-peptide/non-proteinaceous drug for a peptide/proteinaceous drug as claimed.

In response, Applicants respectfully traverse this rejection for the following reasons.

Applicants submit that Suzuki does not teach or suggest the present invention, as discussed above. In addition, Applicants submit that Makino et al. does not teach or suggest a powdery composition where a drug is unevenly dispersed on or in a water-absorbing and water-insoluble base material. Therefore, Suzuki in view of Makino does not teach or suggest the present invention.

Accordingly, Applicants respectfully request that the rejection be withdrawn.

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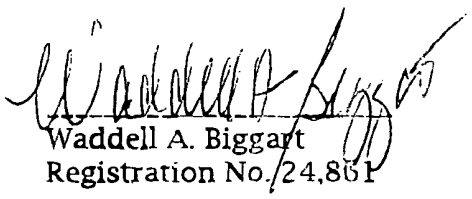
IV Conclusion

In view of the above, reconsideration and allowance of this application are now believed to be in order, and such action is hereby solicited. If any points remain in issue which the Examiner feels may be best resolved through a personal or telephone interview, the Examiner is kindly requested to contact the undersigned at the telephone number listed below.

Applicant hereby petitions for any extension of time which may be required to maintain the pendency of this case, and any required fee, except for the Issue Fee, for such extension is to be charged to Deposit Account No. 19-4880.

Respectfully submitted,



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